

DETAILED ACTION

1. Applicant's amendments in the reply filed on 03/07/2008 is acknowledged and entered into the record.
2. Accordingly Claims 1-3, 11-22, 55-61 are pending. Claims 2, 15, 20-22, 57-61 are withdrawn as being drawn to non-elected inventions/species.
3. Claims 1, 3, 11-14, 16-19, 55 and 56 will be examined on the merits.

Claim Rejections Maintained - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The rejection of Claim 14 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record. The specification, while being enabling for targeting peptides that target prostate cancer tissue comprising amino acids AGG (SEQ ID NO:30), does not reasonably provide enablement for any targeting peptide that comprises SEQ ID NOs: 31-33 and 83-129 (which do not contain SEQ ID NO:30). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. It is also noted that Applicant states in the response filed 03/07/2008 that the "sequences listed in Claim 14 are appropriate dependent sequences in the each includes within their sequences the specific targeting sequence of SEQ ID NO:30. This is not the case, since SEQ ID NOs: 31-33 and 83-129 do not contain SEQ ID NO:30.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 3, 11-14, 16, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Thakur et al. (US Patent 6,395,255).

8. The claims are drawn to a method comprising obtaining an 100 amino acid or less peptide with a cancer targeting motif comprising SEQ ID NO:30 that selectively binds to prostate cancer tissue, attaching an agent to the peptide to form a complex and exposing said complex to a sample of prostate tissue and diagnosing prostate cancer.

9. Thakur et al. teach a method of using a tumor imaging agent to detect tumors (including prostate tumors). The tumor agent is comprised of a composition containing a tumor specific sequence and a radionuclide moiety linked to the tumor specific sequence via a linker, wherein a radionuclide is complexed to radiolabeling moiety. Thakur et al. teach a reagent comprising four amino acids GAGG (SEQ ID NO: 3 and Claim 7, see attached alignment). Although, the agents of Thakur et al. also detect other tumors (colorectal), the claim language is such that any 100 amino acid or less

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peptide having the amino acid sequence of SEQ ID NO:30 would inherently selectively bind to prostate cancer tissue. In addition the step (c) reads on exposing the complex to a population of cells from a normal male patient. Therefore, Thakur teaches the limitations of Claim 1 and dependent claims 3, 11-14, 16 and 17.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thakur et al. in view of Campbell et al. (American J. of Pathol. Vol. 158, pp25-32, 2001) and Schally et al. (The Prostate Vol. 45, pp.158-166, 2000).

13. The claims are drawn to a method comprising obtaining an 100 amino acid or less peptide with a cancer targeting motif comprising SEQ ID NO: 30 that selectively binds to prostate cancer tissue, attaching an agent to form a complex and exposing said

complex to a sample of prostate tissue and diagnosing prostate cancer. The method is also drawn to further comprising categorizing a prostate cancer as androgen-dependent or androgen-independent and expression of IL-11R alpha in the blood vessels of said prostate cancer.

14. The teachings of Thakur et al. are presented in the 102(e) rejection set forth above. Thakur et. al. does not teach categorizing prostate cancer as androgen-dependent or androgen-independent and expression of IL-11R alpha in the blood vessels of said prostate cancer.

15. Campbell et al. teach increased expression of interleukin-11 receptor alpha in prostate carcinoma (see abstract).

16. Schally et al. teach the use of peptide analogs in the therapy of prostate androgen-dependent or androgen-independent cancer (see abstract).

17. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to perform the method of Claim 1 with prostate cancer cells that have been categorized as androgen-independent or androgen-dependent and express IL-11R alpha in their blood vessels. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Thakur et al., Campbell et al., and Schally et al. because Campbell et al. teach that IL-11R alpha is overexpressed in prostate carcinoma and Schally et al. teach that the use of peptide analogs for treatment of androgen-dependent and androgen-independent prostate cancer have been effective.

All other rejections have been withdrawn in view of Applicant's amendments and arguments set forth in the response filed 03/07/2008.

Conclusion

18. Claims 1, 3, 11-14, 16, 17, 55 and 56 are rejected.
19. Claims 18 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MEERA NATARAJAN** whose telephone number is

(571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643